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Letter to the Editor

The conclusion that 'ultramolecular homeopathy has no observable clinical effects' is not supported by the data

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In their article describing an attempt to validate a 'proving' of a homeopathic substance, Brien *et al.* conclude that 'ultramolecular homeopathy had no observable clinical effects' [1]. In our opinion, there are several serious flaws with their unvalidated outcome measure, so that this conclusion is unwarranted, and the results are, for all practical purposes, meaningless.

(1) *There are no observed clinical outcomes*. This study was conducted entirely by mail, including self-administration of the substance, and self-report of symptoms and ancillary factors, such as medication and alcohol use, that might affect health and symptom manifestation. There was no independent observer, as required in any clinical trial. For all practical purposes, this makes the statement 'observable clinical effects' false. The use of postal study methodology for homeopathic provings was begun with a study published in 1993 [2], and most subsequent studies of this topic have used similar methodology. In none of these studies was this methodology validated by comparing standard direct-observation methods with the postal self-report method [3, 4]. In fact, postal research has limited use in clinical studies, and the validity of data obtained by mail has been previously questioned [5, 6].

Independent observation of subjects is essential because the majority of symptoms developed by volunteers (provers) in response to highly diluted substances are subtle and frequently short-lived. Self-reporting subjects may or may not notice these, especially if distracted by other events in their life or if the symptom requires direct observation of the body, such as pupil dilatation, one of the symptoms used in this study. Thus, this study simply perpetuates a well-intended but seriously flawed methodology, despite its having been criticized by previous investigators of the provings model [7].

(2) *Major problems with the symptom list*. The symptoms for this study were selected from a large (over 1700 pages) cross-referenced database [8], which contains 7210 symptom entries for *Belladonna*. Five 'true' symptoms of *Belladonna* are chosen, all without justification. In their pilot study [9], on which the methodology of this study is based, seven true symptoms were used, but, inexplicably, only one of them, in a modified form, appears in the present study. In contrast to the symptoms in the pilot study, which at least reflected fairly general reactions, this study selects narrowly defined symptoms (e.g. 'shooting, tearing pains in my lower limbs that are made better by walking' [1] *vs.* 'tingling or shooting pains in my limbs' [9]). The use of highly specific symptoms instead of more general symptoms, when both are equally true of *Belladonna*, reduces the probability of detecting the symptom, and virtually guarantees that the study will fail to support the proving model, regardless of its validity.

By far the most serious problem with the symptom list is the fact that three of the five 'false' symptoms are actually true symptoms and one 'true' symptom is not a symptom at all:

(a) 'I have had an unusual fear of crowds.' In *Synthesis* [8], the text used in this study for defining symptoms, *Belladonna* is found in the symptom set 'Mind-fear-crowd, in a' [8, p 108].
(b) 'I have a stitching pain in my fingers when I grasp something.' Again, *Belladonna* is found with 'Extremities-pain-stitching-hand' [8, p 1330], and with 'Extremities-pain-stitching-fingers-splinter; as from a' [8, p 1331].
(c) 'Everything tastes bitter except for water.' Although the qualifier 'except for water' is not characteristic, 'Mouth-taste-bitter' [8, p 594] is highly characteristic of *Belladonna*.
(d) One of the 'true' symptoms, 'My lips are inflamed', is not a symptom. Inflammation is a pathological

process and has never been observed in provings. As with many other entries in the repertory [8], it has been reported in accidental poisoning and/or has responded to treatment with Belladonna. A similar reaction to *Belladonna 30C*, however, is highly unlikely.

(3) *The criterion for evidence of a 'proving reaction' is unjustified, unvalidated and inaccurate*. The investigators used the criterion of 'at least 2 true symptoms on at least 2 consecutive days with no more than one false symptom'. This is purely an experimental convenience that does not represent the way provings are historically performed. While an objective outcome is essential in any experimental study, the rationale for this particular outcome is not made clear. Further, some of the symptoms, such as pupil dilatation, could not reasonably be expected to be self-observed or to occur 2 days in a row under any circumstances, particularly with substances that are know to generate subtle and fleeting symptoms. When these problems are combined with the fact that three of the 'false' symptoms are actually true symptoms, and one of the 'true' symptoms is not a symptom, it is obvious that the criterion is totally confounded and meaningless.

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